REMARKS

In the last Office Action, the Examiner objected to the title as being insufficiently descriptive and suggested a new title. The disclosure was objected to as lacking appropriate headings, and the abstract was objected to as not complying with U.S. practice. Claims 12-19 were objected to because they inadvertently depend on canceled claim 1 rather than claim 11. Claim 17 was rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement.

Claims 11-14 and 17 were rejected under 35 U.S.C. §103(a) as being unpatentable over US 4,822,345 to Danforth. Claim 15 was rejected under 35 U.S.C. §103(a) as being unpatentable over Danforth in view of DE 100017147 to Voelker and US 5,706,827 to Ehr. Claim 16 was rejected under 35 U.S.C. §103(a) as being unpatentable over Danforth in view of US 5,630,806 to Inagaki, and claims 19-20 were rejected under 35 U.S.C. §103(a) as being unpatentable over Danforth in view of US 5,337,733 to Bauerfeind, Voelker and Ehr.

Claim 18 was objected to as being dependent upon a rejected base claim and was otherwise indicated to be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

The present invention relates to a guide device for positioning a catheter in a body duct. By way of example, in the embodiment shown in Fig. 2, a guide device 1 according to the present invention comprises a flexible sleeve 13 in which are disposed a first wire thread (elongate body) 2 and a plurality of second wire threads (elongate bodies) 3. The first wire thread 2 is located at the center of the sleeve 13, and the second wire threads 3 are disposed around the outer circumference of the first wire thread 2. The wire threads 2,3 are disposed in side-by-side relation and extend lengthwise along the sleeve 13.

In accordance with the invention, in order to vary the stiffness of the guide device 1, a control device 8 is provided for generating, at will, magnetic fields of different polarities along the first and second wire threads 2 and 3 to bring about a neutral attraction of the wire threads. As shown in Fig. 2, if the first wire thread 2 has a positive polarity and at least some of the second wire threads 3 have a negative polarity, a magnetic attraction exists between the central wire thread 2 and the outer wire threads 3, and the magnetic attraction restricts relative movement between the wire threads 2,3 thereby increasing the stiffness of the guide device 1. The degree of flexibility/stiffness of the guide device can be finely controlled by controlling the number of

the second wire threads 3 to be polarized, the strength of the magnetic fields and the like.

No similar guide device is disclosed or suggested by the prior art. The primary reference to Danforth discloses a guiding catheter whose flexibility/stiffness can be controlled by inflating and deflating a baloon 50 which extends along the exterior surface of a tubular housing 42 (column 5, lines 4-25). There is no disclosure in Danforth of a control device that generates magnetic fields of different polarities along wire threads to selectively bring about mutual attraction of the wire threads, as required by independent claim 11.

In the statement of rejection of claim 11 based on Danforth, the Examiner acknowledges that "Danforth does not specifically disclose the use of first and second wires connected by a control device, which are mutually attracted at will to control the relative movement between the wires." This specific subject matter is a significant part of the claimed guide device and as acknowledged by the Examiner, is not disclosed by Danforth. Nonetheless, the Examiner contends that it would have been obvious to modify Danforth to obtain the claimed guide device in view of the catchall statement at the end of Danforth's specification, at column 7, lines 31-37, which states:

> In still further embodiments of my catheter, the guiding catheter is fabricated from material having properties which change when subjected to light, ultrasound, radio frequency, magnetic fields or other penetrating forces such as electric current. A laser, ultrasound source, etc., is then employed once the catheter is properly positioned to increase its rigidity.

Applicant respectfully disagrees that Danforth renders claim 11 unpatentable. The general statement in Danforth that the guiding catheter could be fabricated from material having properties which change when subjected to magnetic fields is simply too generalized to render obvious claim 11. Applicant is not broadly claiming the use of magnetic fields to control the rigidity of a guide device, but rather is claiming a specific guide device having a first wire thread and one or more second wire threads which are relatively movable and which run close to one another, and a control device connected to the wire threads to control relative movement between the wire threads by generating magnetic fields of different polarities along the first and second wire threads to bring about a neutral attraction of the wire threads. The claimed subject matter would clearly not have been obvious to one of ordinary skill in the art based on the aforequoted statement in Danforth.

In order to support a claim rejection based upon obviousness under 35 U.S.C. §103, the Examiner must provide an evidentiary basis establishing the obviousness of each modification. The Examiner may do this by citing a reference which directly establishes this obviousness, or, the Examiner may otherwise set forth a line of reasoning consistent with and motivated by the cited art establishing that such modifications would have been obvious. Mere speculation or conclusory allegations are simply inadequate to meet this burden. There must be some teaching, reason, suggestion, or motivation found in the prior art references to make a combination which renders an invention obvious within the meaning of 35 U.S.C §103. See, e.g., Symbol Technologies, Inc. v. Opticon, Inc., 935 F.2d 982, 989, 18 USPQ2d 1885 (Fed. Cir. 1991).

In order to set forth a prima facie case of obviousness, the Examiner must not only demonstrate that this teaching exists in the prior art, but that it would teach all limitations of the claim. This burden cannot be met by citing references that, even if combined, fail to teach explicitly recited limitations. Stated otherwise, in rejecting a claim as obvious under 35 U.S.C. §103, the Examiner cannot simply rely on a combination of references that teach some limitations of the claim, and make mere conclusory allegations that the combination teaches others as well.

In the instant case, the Examiner has not met his burden of establishing a prima facie case of obviousness of claim 11 as discussed above.

With respect to dependent claim 12, there is no disclosure in Danforth of making the first wire thread and/or the second wire thread from a magnetizable material or from a non-magnetizable material provided with a magnetizable coating. The limitations of claim 12 are not found in Danforth at column 7, lines 31-37.

Similarly, the limitations in claim 13 that one or both of the first and second wire threads is shaped as a solid body or as a hollow body and when both wire threads are shaped as hollow bodies, the control device generates magnetic fields that interact with a magnetizable fluid inside each wire thread. The statement in Danforth at column 7, lines 31-37, does not disclose these limitations.

Regarding claim 14, since Danforth does not disclose the use of wire threads in the manner recited in base claim 11, the reference does not disclose or suggest applying electric voltage to the wire threads to generate magnetic fields.

Dependent claim 15 specifies that the wire threads are arranged beside each other and parallel to each other, or arranged concentric to each other. In the statement of

rejection, the Examiner contends that it would have been obvious to modify Danforth to use either a parallel arrangement of wire threads as purportedly taught by Ehr in Fig. 6 or a concentric arrangement of wire threads as purportedly taught by Voelker in paragraph 5 for the purpose of controlling the guide device flexibility. Applicant respectfully disagrees. Firstly, since Danforth does not disclose first and second wire threads, the different arrangements of "wire threads" disclosed by the secondary references are of no avail in modifying the non-existent wire threads in Danforth. Secondly, the so-called parallel and concentric wire arrangements in Ehr and Voelker are not arrangements of first and second wire threads in the manner specified in base claim 11.

With respect to dependent claim 16, this requires that the first wire thread is arranged centrally on the inside and several second wire threads are arranged around the outer circumference of the first wire thread. In the statement of rejection, the Examiner proposes modifying Danforth in view of Inagaki, which discloses a spiral wound reinforcement layer, which may comprise flat wire, wound about an inner wall layer. However, the inner wall layer and the spiral wound reinforcement layer do not correspond to the claimed first and second wire threads of base claim 11, which are relatively

movable and which have magnetic fields of different polarities generated along their length to bring about a mutual attraction of the wire threads. Thus even if Danforth were modified in view of Inagaki in the manner proposed, the modified device would not correspond to claim 16.

Dependent claim 17 requires that the wire threads lie flat against each other in response to the magnetic fields to bring about mutual attraction. As Danforth does not disclose first and second wire threads as required by claim 11/17, the reference does not disclose the claimed subject matter. In reply to the Examiner's contention that it is an inherent property of magnets or magnetized materials that when flat wires are magnetized they will lie flat against each other, applicant notes that Danforth does not suggest using magnetizable flat wires (or magnetizable wires of any shape) and therefore Danforth would not have rendered obvious claim 17. Moreover, it is not an inherent property that when flat wires are magnetized they will lie flat against each other. Instead, such a condition would only exist if two flat wires were relatively movable and positioned so that the flat side of one magnet faced the flat side of an opposing magnet, a condition which is not at all described in Danforth.

In response to the rejection of claim 17 under 35 U.S.C. §112, first paragraph, as failing to comply with the

written description requirement, the specification has been amended to describe with reference to Fig. 4 that the first wire thread 2 and the second wire thread 3 lie flat against each other, thereby overcoming this rejection. A similar condition exists, for example, in the embodiment shown in Fig. 3 in which the flat faces of the second wire threads 3 lie flat against opposed flat faces of the first wire thread 2.

With respect to dependent claims 19-20, these include the subject matter of base claim 11 and, in addition, the requirement that the control device enables mutual contact or attachment to each other of the surfaces of the wire threads facing each other, and enables separation of the surfaces from each other through the introduction of a fluid under pressure in a gap between the wire threads. Since Danforth, Voelker and Ehr do not disclose the subject matter of base claim 11, the addition of Bauerfeind does not cure the deficiencies of the other references with respect to teaching the guide device of base claim 11. Therefore even if the references were modified in the manner proposed, they would not result in the claimed guide device.

New independent claim 21 is directed to a guide device comprising a flexible sleeve, a first elongate body and one or more second elongate bodies disposed inside the sleeve in side-by-side relation and extending lengthwise along the

sleeve, and means for selectively creating magnetic attraction and repulsion forces between the first body and the one or more second bodies to vary the stiffness of the guide device. As discussed above with respect to claims 11-17 and 19-20, the prior art of record does not disclose or suggest the guide device recited in claim 21.

Claims 22-27 depend on claim 1 and patentably distinguish over the prior art for at least the same reasons advanced above with respect to claim 21. In addition, claims 22-26 are each believed to be independently patentable on their own merits when read in conjunction with base claim 21.

New independent claim 28 is directed to a guide device and recites a flexible sleeve, a first elongate, stretchable hollow body disposed inside the sleeve and extending lengthwise along the sleeve, plural second elongate bodies disposed inside the sleeve around the outer circumference of the first body and extending lengthwise along the sleeve, the first and second bodies being movable relative to one another to impart flexibility to the guide device, and means for stretching the first body radially outwardly to radially press the second bodies against the inner wall of the sleeve to impart stiffness to the guide device. No similar guide device is disclosed or suggested by the prior art of record. None of the references disclose a centrally located

stretchable hollow body that is stretched radially outwardly to press a plurality of second bodies against the inner wall of a surrounding sleeve to impart stiffness to a guide device.

Dependent claims 29-30 depend on base claim 28 and are therefore likewise patentable.

In view of the foregoing, all grounds of objection and rejection have been overcome. Accordingly, favorable reconsideration and passage of the application to issue are respectfully requested.

Respectfully submitted,

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